Florida Department of Agriculture and Consumer Services
CHARLES H. BRONSON, Commissioner
The Capitol • Tallahassee, FL 32399-0800

Please Respond to:

February 14, 2006

The Honorable Tom Feeney
United States House of Representatives
Washington, DC 20515

Dear Representative Feeney:

I am writing to voice my strong opposition to H.R. 4167, the National Uniformity for Food Act of 2005. As the official charged with food safety oversight in the state of Florida, I feel that this legislation, if passed as it is currently drafted, would severely hamper our ability to protect Floridians from food adulterations. While the stated purpose of H. R. 4167 is to establish uniform standards for food safety warning labels, the bill includes provisions that go far beyond warning labels. It would likely preempt many state food safety laws and regulations that serve as a safety net to protect our citizens.

Currently, states use their laws and regulations to supplement federal regulations or deal with concerns specific to their state, in our case Florida. It is worth noting that the federal government, recognizing that states have more personnel and resources, relies on state agencies to respond quickly to food borne illness outbreaks and perceived bioterrorists threats. Congress has repeatedly recognized that states can respond quicker to events than can federal agencies. Preparedness grants to states that are provided under the Department of Homeland Security are a good example of this. H.R. 4167 would undermine the authorities we use to respond to these events and, by implementing bureaucratic petitioning processes, create additional burdens on already strained state budgets.

Much of the language included in H.R. 4167 is ambiguous, failing to clearly limit the intent to food labeling. When this bill was introduced in the 108th Congress as H.R. 2699, our attorneys conducted a detailed analysis of how it could affect Florida's Food Safety Act. I have included that analysis with this letter for your information. I should mention that Florida's legal analysis of the language is consistent with the conclusions reached by 10 other states.

I want to state clearly that the Florida Department of Agriculture and Consumer Services is not opposed to uniform labeling. Rather, it is the provisions in H.R. 4167 not related to labeling that I am concerned about. These provisions would restrict a state from using its statutes and authorities to address food adulterations (harmful components that cause a public health risk). If public health is to be protected, it is imperative that states be able to respond quickly to contaminated products without seeking federal permission, and without embarking on a lengthy petitioning process.

To give you an example of the type of authority that would be at risk if H.R. 4167 were to pass as written, the Food and Drug Administration (FDA) has adopted few adulteration standards for microbial contaminants in foods. While they have issued some guidance in this area, adulteration is frequently determined on a case by case basis. States already confer with FDA whenever a food safety action is undertaken. FDA's authority, however, does not allow it to stop the sale of suspected product unless or until the Secretary declares an emergency. Under H.R. 4167, a state would not only confer with FDA but actually have to wait for some kind of decision from them before embarking on any action. Waiting for FDA approval would cause a significant delay and places Florida's citizens and visitors at an unacceptable risk.

H.R. 4167 would preempt a state from enforcing any law relating to food safety that is not identical to the Federal Food, Drug, and Cosmetic Act. It would place at risk our cooperative programs for milk, dairy and shellfish, which operate under the auspices of both the Public Health Services Act and the Federal Food Drug and Cosmetic Act (FFDCA) and which are designed to ensure uniform standards across all fifty states. These programs are based on model codes, ordinances and standards which are developed by a conference body and recommended by but not adopted as rule by FDA. Under this bill, states without laws identical to the FFDCA laws defining adulterated food would lose their legal foundation for adopting these model ordinances and conducting these cooperative programs.

Finally, H.R. 4167 would make it more difficult mitigate the effects of an intentional bioterrorist agent food adulteration. Because there are no standards for acceptable levels of bioterrorism agents in foods, a state would not be able to take any action without first completing the lengthy petitioning process included in H.R. 4167. Under current law, the state would act as a "first responder" until FDA has secured the proper Secretarial authority.

Because H.R. 4167 does not clearly deal exclusively with food labeling, it has the potential to cut the food safety net that has been constructed to protect the health and well being of our citizens. I urge you to oppose passage of this bill as it is currently drafted. I appreciate your willingness to consider the Department's concerns in this matter. If you have any questions or need more detailed information, please contact Leslie Palmer in my office at 850-488-3022.

Sincerely,

Charles Bronson

CHARLES H. BRONSON
COMMISSIONER OF AGRICULTURE

Effect on Florida's Food Safety Statutes with passage of H.R. 2699, the National Uniformity for Food Act of 2003

The Florida Department of Agriculture and Consumer Services, Office of General Counsel was requested to review and analyze HR 2699, a bill currently under review by the Subcommittee on Health of the U.S. House Committee on Energy and Commerce to determine what impact it would have on Florida's food safety laws, specifically the "Florida Food and Safety Act," Chapter 500, Florida Statutes.

This analysis discusses and compares the salient provisions of HR 2699 with Florida Statutes and the effect that HR 2699 would have if enacted upon Florida food safety law.

DISCUSSION AND ANALYSIS OF HR2699 AND ITS EFFECT ON FLORIDA FOOD SAFETY LAW:

The bill appears to be neither specific nor limited in its scope. The purpose of the bill is stated to be: "To amend the Federal Food, Drug and Cosmetic Act to provide for uniform food safety warning notification requirements and for other purposes." The concern is the "other purposes." While the intent of the proposed legislation may be uniformity, its ultimate effect may be to invalidate many State laws and regulations which now supplement federal regulation or deal with local concerns.

ANALYSIS:

21 U.S.C. Section 343-1(Section 403A, Federal Food, Drug and Cosmetic Act)

The first section amended is 21 U.S.C. Section 343-1[National Uniform Nutrition Labeling.] When read with the Section's introductory language the amendments are as follows:

> *"(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce-*
>
> ***
>
> *(6) any requirement for a food described in section 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7), 402(c), 404, 406, 409, 512, or 721(a), that is not identical to the requirement of such section.*
>
> *For purposes of paragraph (6) and section 403B, the term "identical" means that the language under the laws of a State or a political subdivision of a State is substantially the same language as the comparable provision under this Act and that any differences in language do not result in the imposition of materially different requirements."*

Subsection (a) (6) of the proposed amendment pre-empts not just labeling but "any requirement for a food" described in the enumerated sections of the Federal Food, Drug and Cosmetic Act (FFDCA). The additional paragraph that was added to subsection (a) (6) in HR 2699 appears to be an attempt to eliminate any misunderstandings about the meaning of "identical." It means identical language or language that is substantially the same. If any difference in language results in a materially different requirement, it is not identical.

"REQUIREMENT" MEANS BOTH LAWS AND REGULATIONS

The term "requirement" as used in HR 2699 is defined in Section 403B (b) (2) (h) of the

proposed legislation as follows:

> *"In section 403A and this section (1) the term "requirement" used with respect to a Federal action or prohibition, means a mandatory action or prohibition, established under this Act or the Fair Packaging and Labeling Act (15 U.S.C. Section 1451 et.seq.) as appropriate or by a regulation issued under or by a court order relating to, this Act or the Fair Packaging and Labeling Act, as appropriate."*

Proponents of S 1155, (a similar bill, not enacted) which contained the same definition, stated that the term "requirement" as defined includes an action or prohibition mandated under the federal system by virtue of either a regulation or a court order. To qualify as a "requirement" the federal policy would not have to be enacted through formal (notice and comment), unless it came into being through a court order. The proponents further stated that policies existing through informal means (e.g. action levels) would not qualify as requirements. What isn't clearly stated is what a State or its political subdivisions might do that would be classified as a requirement for food. **The implication is that either a state law or an administrative rule regarding food adopted by a state agency would be classified as a requirement. If the statute or rule involved any of the subjects in the enumerated sections of the FFDCA that would become pre-emptive if HR 2699 were enacted, the state law or rule would have to be identical.**

COMPARISON OF FEDERAL LAWS THAT WOULD BE AMENDED BY HR 2699 WITH FLORIDA FOOD AND SAFETY ACT, CHAPTER 500, FLORIDA STATUTES

Following is a list of the enumerated sections of the FFDCA cited with a comparison of the effected section of the "Florida Food and Safety Act", Chapter 500, et. seq., Florida Statutes.

* 402(a) (1) [21 U.S.C. Section 342(a) (1) - Adulterated Food/Poisonous, unsanitary, etc. ingredients]. *"If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."*

Section 500.10 (1(a), Florida Statutes, is identical.

*402(a)(2) [21 U.S.C. Section 342 (a)(2)-Adulterated Food/Poisonous, unsanitary, etc. ingredients] *"(A) If it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of Section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of Section 346(a) of this title: or (C) if it is or it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title."*

Section 500.10 (1(b), Florida Statutes is NOT identical.

*402(a) (6) [21 U.S.C Section 342 (a) (6)-Adulterated food/Poisonous, unsanitary, etc.

ingredients]. *"If its container is composed, in whole or in part, of any poisonous or deleterious substance, which may render the content injurious to health."*

Section 500.10 (1) (h) is identical.

*402 (a) (7) [21 U.S.C. Section 342 (A) (7)-Adulterated food/Poisonous, unsanitary, etc. ingredients.} *"If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title."*

Florida has no similar law.

*402 (C) [21 U.S.C. Section 342 (c)-Adulterated food/Color additives]. *"If it bears, or contains, a color additive which is unsafe within the meaning of section 721(a)."*

Section 500.10 (4), Florida Statutes, almost but NOT identical, states: "If it bears or contains any color additive which is unsafe within the meaning of the federal act or s. 500.13"

*404 [21 U.S.C Section 344- Emergency Permit Control].

Florida has no similar law.

*406 [21 U.S.C. Section 346-Tolerances for poisonous or deleterious substances in food; regulations].

Section 500.13, Florida Statutes is NOT identical.

*409 [21 U.S.C. Section 348-Food additives].

Section 500.13, Florida Statutes is NOT identical.

*512 [21 U.S.C. Section 360b-New Animal Drugs].

There is no similar Florida law.

Note: Section 580.071 (c) provides that commercial feed or foodstuff shall be deemed to be adulterated "If it is, or it bears or contains, any food additive or color additive that is unsafe within the meaning of s.409 or s.512 of the Federal Food, Drug and Cosmetic Act, respectively."

Section 580.071 (e) provides that any commercial feed or foodstuff shall be deemed to be adulterated "If it is, or it bears or contains, any new animal drug that is unsafe within the meaning of s.512 of the Federal Food, Drug and Cosmetic Act."

* 721(a) [21 U.S.C. Section 379e-Listing and certification of color additives for foods, drugs, devices and cosmetics].

No identical Florida law.

Section 500.10 (4), Florida Statutes provides that a food is deemed to be adulterated "If it bears or contains any color additive which is unsafe within the meaning of the federal act or s.500.13."

Section 500.13 (2), Florida Statutes, however, provides in part that the Department can adopt, amend or repeal regulations "whether or not in accordance with regulations promulgated under the federal act" prescribing tolerances for color additives.

The result of the addition of subsection (a) (6) of the amendment as proposed to 21 U.S.C. Section 343-1 [403A of the Federal Food, Drug and Cosmetic Act] would be that the Department would be preempted from any requirements regarding federal sections cited which differ from federal requirements. It appears that several sections of the Florida

Food Safety act might be invalidated as well as some of the Department's regulatory provisions. The federal preemption would be very broad because virtually all food safety requirements are premised upon "poisonous or deleterious substance which may render [them] injurious to health."

SPECIFIC EXAMPLES OF HR 2699'S POTENTIAL EFFECT ON FLORIDA'S FOOD SAFETY LAWS

What may be of more concern are not those substances the federal government regulates in detail but what it does not regulate in detail, as discussed in the two examples cited below:

1. Any dietary supplement containing ephedra or ephedrine or its alkaloids in excess of 25 mg/dose or 125mg/day is considered by the Department to be adulterated and a stop sale is issued. This is based on Section 499.033, Florida Statutes that prohibits the sale of over the counter drugs containing more than this without a prescription. FDA did not view dietary supplements containing ephedra in this same manner, since they were regulated as a food, not a drug. Federal regulation was proposed in 1997 that would fix this, and the comment period was re-opened in February, 2003 but no similar rule has yet been promulgated by the federal government. On December 30, 2003 FDA issued a consumer alert and announced its intent to publish a rule which would have the effect of banning the sale of dietary supplements containing ephedra. The rule will become effective 60 days following its publication. This is a classic example of how it can take the federal government much longer than the states to react to a dangerous or potentially dangerous food safety problem.

2. There is no tolerance for chloramphenicol because there is no legitimate use in food animals. Florida, along with other states, were aware of the potential for chloramphenicol tainted seafood to be sold in the U.S , following its discovery in Europe. The Department moved more quickly than the FDA and developed detection methodology that was ultimately adopted by the FDA. Based on its laboratory method, the Department was able to identify and using its stop sale authority was able to act **immediately** to protect our citizens. The Department worked collaboratively with FDA, but it must be noted that FDA regulatory response required seizure through a court injunction – a much more time consuming and expensive procedure. **It is questionable whether the Department could act in the absence of a federal rule if HR 2699 were passed.**

21 U.S.C. Section 343-2[Section 403B of the FFDCA]

The second section amended is Section 403B of the FFDCA, 21 U.S.C Section 343-2[Uniformity in Food Safety Warning Notification Requirements]. Under subsection (a) all States and their political subdivisions would be preempted from providing notification requirements for food safety warnings or food packaging unless the notification requirements were identical to those prescribed under the FFDCA.

Subsection (b) and (c) (1) would allow States to petition for exemptions from the requirements of subsection (a) or paragraph 6 of 21 U.S.C. Section 343-1(Section 403A (6) of the FFDCA). The Secretary *"may provide such an exemption, under such conditions as the Secretary may impose for such a requirement that -(A) protects an important public interest that would otherwise be unprotected, in the absence of the exemption; (B) would not cause any food to be in violation of any applicable requirement or prohibition under Federal law; and (C) would not unduly burden interstate commerce, balancing the importance of the public interest of*

the State or political subdivision against the impact on interstate commerce."

Subsection (c)(2) provides that any State may petition the Secretary to establish by regulation a national standard respecting any requirement under this Act or the Fair Packaging and Labeling Act, 15 U.S.C. Section 1451 et. Seq. relating to the regulation of a food.

While subsection (c) (1) provides the three broad general criteria which must be met to qualify for an exemption, subsection (c) (2) relating to petitions for national standards has no such broad general criteria for judging the petition. **Neither section lists criteria for evaluation of a petition.** There is wide discretion in both (c) (1) and (c) (2) for the Secretary to evaluate and impose conditions.

Publication of petitions and time frames for acting on the petitions are provided as is judicial review. The time period for petitions for existing State requirements, both for filing (180- days after enactment of HR 2699) and for the Secretary to act upon it (up to a maximum of two years after enactment of HR 2699) is significantly longer than for petitions for new requirements(Secretary has a maximum of 210 days from receipt of the petition to act). **However, without criteria for the petitions themselves, and with discretion in the Secretary to impose conditions, the benefit of these procedural safeguards to the States is questionable.**

IMMINENT HAZARD AUTHORITY

Section 403 B (d) of the proposed legislation "Imminent Hazard Authority" provides a procedure to be followed should a State choose to establish a "requirement that would otherwise violate paragraph (6) or (7) of Section 403 A (a) or subsection (a), if (A) the requirement is needed to address an imminent hazard to health that is likely to result in serious adverse health consequences or death;"

The State must 1) notify the Secretary; 2) the Secretary must not have initiated enforcement action with respect to the matter; 3) a petition must be submitted for an exemption or national standard relating to the requirement and, 4) the State must initiate enforcement within 30 days after the State establishes the requirement.

The Secretary has to take action on any petition relating to an imminent hazard within 7 days of receipt. Failure to do so will constitute final agency action for the purpose of judicial review. A reviewing court can direct the Secretary to comply. The State requirement would remain in effect until the Secretary takes final agency action on the matter.

This provision would afford a State an opportunity to initiate a stop sale or other emergency state procedure, even if it did not comport with the pre-emptive federal law. Of course the State's freedom to act promptly in the interest of its citizens is subject to complying with Section 403 B (d) of the proposed legislation. Such requirements are exceedingly cumbersome, and of questionable benefit to the state.

WOULD A STATE HAVE TO ADOPT EMBARGO PROCEDURES SIMILAR TO THOSE OF THE FEDERAL GOVERNMENT IF HR 2699 IS ENACTED?

Sections 404,406, 409 and 512 of the proposed legislation set forth procedures to be followed, not merely standards. The procedures under State law would presumably have to be identical.

Section 403B (a) (3) of the proposed legislation states:

" (3) CONSTRUCTION.-Nothing in this section shall be construed to prohibit a State from conducting the State's notification, disclosure, or other dissemination of information , or to prohibit any action taken relating to a mandatory recall or court injunction involving food adulteration under a State statutory requirement identical to a food adulteration requirement under this Act."

While at first glance it seems to be preserving something for the States, **if the pre-emptive federal provision is procedural, then the State law to be identical has to have the same federal procedures. If one of the pre-empted areas is involved, then probably the Florida procedures including embargo and injunction will have to be identical to the procedures of the federal laws.** The federal food safety laws do not have a "stop sale provision" similar to Florida's. The Department's authority to stop sale in the areas that have been pre-empted may be lost if it is determined by the Courts that the scheme of federal regulation in the areas pre-empted is so pervasive that Congress intended that there be no room left for the states to supplement it with their own laws. State of Florida vs. Stepansky, 761 So2d 1027, 1033, 1034 (Fla.2000)

CONCLUSION:

It is difficult to predict what will occur if this law is passed however the federal preemptions proposed in HR 2699 go far beyond uniform food safety warnings. States and their political subdivisions may be preempted from enacting any requirement for a food with regard to a poisonous or deleterious substance which may render the food injurious to health, etc. Under HR 2699, as it is presently drafted, States arguably would be preempted from enacting any statutory law or regulation regarding food safety which is not identical to the federal standard. While the Florida Food Safety Act, Chapter 500, et. seq., Florida Statutes has adopted many of the provisions of the FFDCA, the provisions of Chapter 500 et. seq., Florida Statutes are NOT identical to those of the FFDCA nor are the Department's regulations.

If passed, HR 2699 would result in a substantial loss of power by the State to fashion laws and regulations relating to food safety for their citizens, particularly those enabling the State to react quickly to a perceived food safety emergency involving an adulterated food. This includes the Department's ability to respond to bio-terrorist threats and other domestic security issues involving food safety. The Department, unlike the FDA, has authority to take immediate agency action under State law. The FDA on the other hand is bound by the FFDCA and often must resort to federal courts for enforcement action which is more cumbersome and expensive.

There appears to be a legitimate basis for concern. HR 2699 reaches beyond the stated purpose of providing uniformity in food safety warning notification requirements. It is not limited in its scope but is broadly written to encompass and preempt numerous powers exercised by the States in the area of food safety. Lastly, while this analysis has focused mostly upon the bill's effect on Chapter 500, Florida Statutes, there appears to be valid concerns regarding the bill's effect on the Department's other food programs and its ability to immediately respond to domestic security threats.